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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,882	12/10/2001	Heidi Meyer	V-261.00	2886
7590 02/24/2004				
Baxter Healthcare Corporation P.O. Box 15210 Irvine, CA 92614			EXAMINER CHEN, STACY BROWN	
			ART UNIT 1648	PAPER NUMBER
DATE MAILED: 02/24/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/006,882

Applicant(s)

MEYER ET AL.

Examiner

Stacy B Chen

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1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicant's response and amendment filed December 4, 2003 is acknowledged and entered. Claims 1-21 are pending and examined. The rejection of claims 3-5, 10, 15-16 and 20 under 35 U.S.C. 112, second paragraph, is withdrawn in view of Applicant's amendment. The rejection of claims 1, 2, 4, 5, 8, 9, 11-13, 15, 16, 18 and 19 under 35 U.S.C. 102(b) as anticipated by Kistner *et al* (WO 96/15231) is withdrawn in view of Applicant's amendment. The rejection of claims 3, 6, 7, 14, 17 and 21 under 35 U.S.C. 103(a) as being unpatentable over Kistner *et al* (WO 96/15231), in view of Purcell *et al* (4,894,228), Leu *et al* (WO 95/24468), Pellegrini *et al* (5,607,851) and Shih *et al* (5,980,901) is withdrawn in view of Applicant's amendment. The following new grounds of rejection are applied in view of Applicant's amendment filed December 4, 2003.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims as amended are drawn to a method for continuous production of Hepatitis A virus (HAV) comprising the steps of providing a serum free cell culture of VERO cells bound

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to a microcarrier, infecting said culture with HAV, incubating the infected cells at a reduced temperature, and harvesting the HAV released into the cell supernatant. The specification does not teach a method wherein the reduction of temperature takes place after infection. Claims 1, 12 and 13 indicate that the reduction in temperature occurs after post-infection. However, the specification at paragraph [018] teaches that the reduction in temperature occurs prior to infection, as claimed in claims 3 and 13. The reduction in temperature prior to the step of infection appears to be critical to the claimed invention, since virus propagation is to be performed at the reduced temperature. The specification nowhere teaches that the temperature is reduced post-infection. According to the specification, a temperature reduction post-infection would be counterproductive, since the propagation of viruses should take place at the reduced temperature. Therefore, the amended claims lack support in the specification for the full scope being claimed.

3. Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claims 1 and 12 recite the limitation “reduced temperature” which lacks comparative basis. The claims should indicate what temperature the “reduction” is being compared to.
- Claims 1 and 12 recite “HAV is continuously released into the cell culture medium and infected cells release at least 50% of viral antigen into the cell supernatant; and harvesting said HAV released into the supernatant of the cell

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culture medium.” It is not clear what the difference is between the continuous release of HAV into the medium, and the release of HAV from infected cells into the supernatant. The claim as amended infers that only virus released from infected cells into the supernatant is harvested, however, it seems that virus released into the cell culture would also be harvested. Clarification is requested regarding these particular method steps.

- Claims 3 and 13 recite the limitation “said reduced temperature is about 34°C prior to infection”. However, claims 1 and 12, from which claims 3 and 13 depend, respectively, are drawn to a method wherein the reduction of temperature occurs post-infection.

Conclusion

4. No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

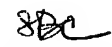
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,


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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers relating to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 located in Crystal Mall 1. The Fax number for Art Unit 1648 is (703) 872-9306. All Group 1600 Fax machines will be available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stacy B. Chen, whose telephone number is (571) 272-0896. The Examiner can normally be reached on Monday through Friday from 7:30 AM-4:00 PM, (EST). If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, James C. Housel, can be reached at (571) 272-0902. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Stacy B. Chen
February 20, 2004


JAMES HOUSEL 2/23/04
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600